

PATENT COOPERATION TREATY

10 Rec'd PCT/PTO

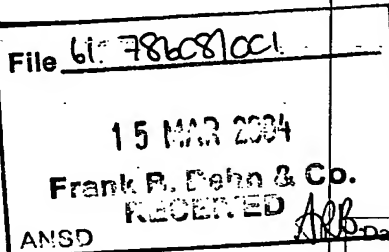
JAN 2004

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

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10 Rec'd

WRITTEN OPINION
(PCT Rule 66)

Applicant's or agent's file reference		Date of mailing (day/month/year) 12.03.2004
International application No. PCT/GB 03/02928		REPLY DUE within 3 month(s) from the above date of mailing
International filing date (day/month/year) 07.07.2003	Priority date (day/month/year) 10.07.2002	
International Patent Classification (IPC) or both national classification and IPC C07K1/22, C07K1/22		
Applicant NATIONAL BLOOD AUTHORITY et al.		

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application
3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is:

DUE DATES
NOTED

12/6/04

Name and mailing address of the international preliminary examining authority:

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I. Basis of the opinion

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

Description, Pages

1-34 as originally filed

Claims, Numbers

1-20 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
 - ☐ the language of publication of the international application (under Rule 48.3(b)).
 - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority in written form.
 - ☐ furnished subsequently to this Authority in computer readable form.
 - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
4. The amendments have resulted in the cancellation of:
- ☐ the description, pages:
 - ☐ the claims, Nos.:
 - ☐ the drawings, sheets:
5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).
6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 11-20

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☒ the description, claims or drawings: *(indicate particular elements below)* or said claims Nos. 11-20 are so unclear that no meaningful opinion could be formed *(specify)*:

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1,3,8,9
Inventive step (IS)	Claims	2,4-7,10
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

Section III

- 1) The subject-matter of claims 11 and 12 is defined by the process of producing fibrinogen rather than by the technical features of the particular fibrinogen preparation. As such, the scope of said subject-matter is unclear to such an extent that a meaningful examination is not possible. Claims 13 - 20 relate back / are dependent on said claims.
- 2) Some of the features in the kit claim 14 relate to a method of producing the kit rather than clearly defining the kit in terms of its technical features. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT.
- 3) The dependency of claim 14 on a kit as claimed 12 is obviously erroneous (Art. 6 PCT).

Section V

- 1) Reference is made to the following documents:
 - D1: JP(A) 02193913
 - D2: Millipore Product Catalogue - Product Category Prosep Chromatography Media (1999), , 1-2
 - D3: Haemophilia: The Official Journal Of The World Federation Of Hemophilia. England Nov 2000 (11-2000), 6(6), 705-708
 - D4: Derwent WPI; AN: 1996-112641(JP(A) 8012586)
 - D5: WO-A-9012803
 - D6: Journal Of Biomedical Materials Research (05-2000), 50(2), 110-113
 - D7: Derwent WPI; AN: 1997-095485(JP(A) 8333387)
- 2) The present application does not satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of claims 1, 3, 8 and 9 is not new in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

It is known from D1 and D2 (section headed "Prosep Chelating I, II and III) that

fibrinogen binds to metal chelating chromatography media. Since D5 (page 21) also proposes to purify fibrinogen with an immobilized metal affinity chromatography resin, it is considered that each of D1, D2 and D5 constitutes an enabling disclosure prejudicial to the subject-matter of the above mentioned claims.

- 3) The present application does not satisfy the criterion set forth in Article 33(3) PCT because the subject-matter of claims 7 and 10 does not involve an inventive step (Rule 65(1)(2) PCT).

In view of the statement in D2 (loc.cit.) that large molecules can be purified by IMAC, the subject-matter of claims 7 and 10 would appear to lack an inventive step (Art. 33(3) PCT).

- 4) Dependent claims 2 and 4 - 6 do not appear to contain any additional features which, in combination with the feature of the claim(s) to which they refer, involve an inventive step. Said claims cannot be accepted under Article 33(3) PCT.
- 5) Note in relation to claims 11 - 20:

It would appear that the use of fibrinogen in therapy is known in the prior art. A new process of producing a known product (eg plasminogen free fibrinogen) cannot render the said product novel. As regards claims 14 and 16: replacement therapy in afibrinogenaemia as well as virus inactivation of pharmaceutical compositions derived from human blood is known to the skilled person (see documents cited in the present application).

- 6) Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 - D5 is not mentioned in the description, nor are these documents identified therein.